

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

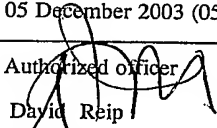
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Applicant's or agent's file reference 4510-6-PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US02/31201	International filing date (day/month/year) 30 September 2002 (30.09.2002)	Priority date (day/month/year) 28 September 2001 (28.09.2001)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 17/70 and US Cl.: 606/61		
Applicant STEPHEN RITLAND		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the report
 - II ☐ Priority
 - III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 28 April 2003 (28.04.2003)	Date of completion of this report 05 December 2003 (05.12.2003)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer  David Reip Telephone No. 703-308-0858

Form PCT/IPEA/409 (cover sheet)(July 1998)

I. Basis of the report**1. With regard to the elements of the international application:***

- ☐ the international application as originally filed.
- ☒ the description:
pages 1-37 _____ as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the claims:
pages none _____, as originally filed
pages NONE _____, as amended (together with any statement) under Article 19
pages NONE _____, filed with the demand
pages 38-49 _____, filed with the letter of 13 October 2003 (13.10.2003)
- ☒ the drawings:
pages 1-17 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☒ the claims, Nos. 2, 3, 14
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US02/31201**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>1, 4-13, and 15-84</u>	YES
	Claims _____	NO
Inventive Step (IS)	Claims <u>1, 4-13, and 15-84</u>	YES
	Claims _____	NO
Industrial Applicability (IA)	Claims <u>1, 4-13, and 15-84</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1, 4-13, and 15-84 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest devices, tools, and methods having all the limitations as recited in the claims. For example, with respect to claim 1, the prior art fails to disclose or suggest a surgical implant assembly having all the limitations as recited in claim 1, including wherein the second end of the attachment device comprises a hollow core bordered by curved walls, the second end having a central aperture contiguous with the hollow core, the second end further including at least a second opening wherein the second opening is an expansion slot or entry channel.

Claims 1, 4-13, and 15-84 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----

What is claimed is:

1. A surgical implant assembly, comprising:

an attachment device having first and second ends, said second end having a hollow core bordered by curved walls, said second end having a central aperture contiguous with
5 said hollow core, said second end further including at least a second opening wherein said second opening is an expansion slot or an entry channel;

a tension link having a proximal end and a distal end, said proximal end having a tension link head and said distal end being threaded, said tension link head rotatably mounted within said hollow core and maintained therein by contact with said curved walls; and

10 a rod having at least one preformed socket adapted for at least partially receiving said second end, said socket including at least one tension link cavity, wherein said rod is secured to said attachment device by a tension link nut that is threaded onto said distal end of said tension link.

2. Canceled.

- 15 3. Canceled.

4. The surgical implant assembly of claim 1, wherein said first end of said attachment device includes threads.

5. The surgical implant assembly of claim 1, wherein said socket is at least partially spherical in shape.

20 6. The surgical implant assembly of claim 1, wherein said socket is located at the end of said rod.

7. A method of installing a surgical implant assembly, comprising the steps of:

(a) securing an attachment device to human bone, the attachment device having a shank with first and second ends, the second end having a hollow core and a central aperture, said second end further including at least a second opening comprising an entry
25 channel operatively connected with the hollow core;

(b) inserting a tension link head of a tension link into the hollow core of the attachment device, the tension link having a tension link shaft that extends through the central aperture of the attachment device;

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(c) seating a rod having a connecting receptacle onto the second end of the attachment device by passing the tension link shaft through a tension link cavity within the connecting receptacle; and

(d) securing the rod to the attachment device by threading and tightening a tension
5 link nut onto the tension link shaft.

8. The method of claim 7, further comprising the step of adjusting an angular relationship between the attachment device and the connecting receptacle.

9. The method of claim 8, wherein said adjusting step occurs between steps (c) and (d).

10 10. The method of claim 7, wherein said inserting step further comprises inserting the tension link shaft through the entry channel and the hollow core, and pulling the tension link shaft through the central aperture until the tension link head is positioned in the hollow core.

11. A method of installing a surgical implant assembly, comprising the steps of:

15 (a) securing an attachment device to human bone, the attachment device having a shank with first and second ends, the second end having a hollow core and a central aperture, said second end further including at least a second opening comprising an entry channel having an entrance operatively connected with the hollow core, and a tension link slot through the second end to the hollow core between the entry channel and the central
20 aperture;

(b) inserting a tension link head of a tension link into the hollow core of the attachment device, the tension link having a tension link shaft that extends through the central aperture of the attachment device, said inserting step comprising placing the tension link head at the entrance of the entry channel, inserting the tension link shaft into the tension
25 link slot such that the tension link shaft is located within the central aperture, and pulling the tension link head into the hollow core;

(c) seating a rod having a connecting receptacle onto the second end of the attachment device by passing the tension link shaft through a tension link cavity within the connecting receptacle; and

30 (d) securing the rod to the attachment device by threading and tightening a tension link nut onto the tension link shaft.

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12. In subcombination, a low-profile medical device connector used to connect a piece of hardware to a spine, the device used in combination with a tension link having a tension link head and a tension link shaft that threadably receives a tension link nut, and in combination with an attachment device having an enlarged substantially spherical shaped area with a hollow core for receiving the tension link head, a central aperture for passing the tension link shaft therethrough, and at least a second opening wherein the second opening is an expansion slot or an entry channel, said connector device comprising:

a rod portion including a rod member for aligning substantially parallel to the spine and for at least partially spanning at least one disk of the spine, said rod portion further including a receptacle attached to said rod member, said receptacle including a substantially semi-spherical shaped socket adapted to receive the enlarged substantially spherical shaped area of the attachment device, said receptacle having a tension link cavity for passing the tension link shaft therethrough;

wherein said socket is rotatable over said enlarged substantially spherical shaped area of the attachment device before securing said rod portion to said attachment device, and wherein said rod portion is secured to the attachment device by tightening the tension link nut on the tension link shaft after passing the tension link shaft through said tension link cavity upon placement of said receptacle over the attachment device.

13. A tool for inserting a pedicle screw into a pedicle of a vertebra, the pedicle screw having a first end that is threaded and a second end that is an enlarged area having a hollow core, the hollow core including at least one of either an expansion slot, a tension link slot, or an entry channel, the tool comprising:

a hollow shaft for receiving a tension link shaft of a tension link pre-positioned in the hollow core of the pedicle screw;

a receptacle adapted for mating with the enlarged area of the pedicle screw; and a projection located within said receptacle, the projection adapted for mating with at least one of either the expansion slot, the tension link slot, or the entry channel of the pedicle screw;

wherein the tool is rotated to provide torque to the second end of the pedicle screw and drive the first end of the pedicle screw into the pedicle of the vertebra.

14. Canceled.

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15. The tool as claimed in claim 13, further comprising an handle for grasping said tool.

16. The tool as claimed in claim 13, further comprising means for temporarily restraining the pedicle screw, said means located within said receptacle.

5 17. The tool as claimed in claim 16, wherein said means comprises a material selected from the group consisting of a nylon insert and a teflon insert.

18. The tool as claimed in claim 13, further comprising means for rotating said receptacle.

10 19. An attachment device adapted for use with a tension link, the tension link including a tension link head having a truncated area, the device comprising:

a shank having first and second ends,

said first end having a securing mechanism, and

15 said second end comprising a hollow core, an entry channel having a truncated surface, and a central aperture operatively associated with said hollow core and said entry channel, wherein said entry channel is sized for receiving the tension link, and said central aperture is sized for retaining the anchoring shaft head within said hollow core, and wherein the truncated area of the tension link head must be substantially aligned with said truncated surface of said entry channel to insert or remove the tension link head from said hollow core.

20 20. A connector as in claim 19, wherein said second end further comprises at least one expansion slot operatively associated with said central aperture.

21. A connector device as in claim 19, wherein said securing mechanism is selected from the group consisting of screw threads, hooks, plates, and flanges.

22. A connector device as in claim 19, wherein said hollow core has an interior surface, said interior surface having a texture.

25 23. A connector device as in claim 19, wherein at least a portion of the second end of said connector device has a shape selected from the group consisting of: spherical, semi-spherical, aspherical, polyhedral, conical, and a truncated cone shape.

24. A surgical implant assembly attachable to an existing rod member, comprising:

30 an attachment device having first and second ends, said second end comprising a hollow core including a central aperture, and at least either one expansion slot or an entry channel;

a tension link having a proximal end and a distal end, said proximal end having a tension link head and said distal end being threaded, said tension link head insertable into said hollow core through said entry channel or through said central aperture by expanding said expansion slot, said tension link head retained within said central aperture;

5 a clamp connection attachably securable to the existing rod member, said clamp connection permitting adjustable positioning of a portion of the existing rod member within said clamp connection during implantation of said assembly, said clamp connection having at least one tension link cavity;

10 wherein a link nut is threaded onto said distal end of said tension link to secure said clamp connection to the existing rod member and said attachment device.

25. The surgical implant assembly of Claim 24, wherein said clamp connection comprises a lower clamp portion and an upper clamp portion.

26. The surgical implant assembly of Claim 25, wherein said lower clamp portion and said upper clamp portion each include a securing end.

15 27. The surgical implant assembly of Claim 26, wherein said securing end include a receptacle.

28. The surgical implant assembly of Claim 25, wherein said lower clamp portion and said upper clamp portion include a clamp region.

20 29. The surgical implant assembly of Claim 28, wherein at least one said clamp region comprises at least one ridge.

30. A bone stabilization device for securing a first bone segment to a second bone, the first bone segment having been fitted with a first attachment device and the second bone segment having been fitted with a second attachment device, the stabilization device comprising:

25 a first rod member;

a first interconnection mechanism for attaching said first rod member to the first attachment device;

a second rod member including a compression zone that operatively engages at least a portion of said first rod member; and

30 a second interconnection mechanism for attaching said second rod member to the second attachment device;

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wherein said compression zone of said second rod member is placed into compression against said at least a portion of said first rod member by tightening said second interconnection mechanism against said second rod member.

5 31. The stabilization device as claimed in claim 30, wherein the second rod member comprises at least two portions.

32. The stabilization device as claimed in claim 31, wherein said at least two portions include substantially half-cylinder sections.

33. The stabilization device as claimed in claim 32, wherein at least a portion of said half-cylinder sections at least partially surround a portion of said first rod member.

10 34. The stabilization device as claimed in claim 31, wherein said at least two portions each include an opening for receiving said first rod member.

35. The stabilization device as claimed in claim 30, wherein said first interconnection mechanism includes a tension link.

15 36. The stabilization device as claimed in claim 35, wherein said first interconnection mechanism includes a tension link nut.

37. The stabilization device as claimed in claim 30, wherein said second interconnection mechanism includes a tension link.

38. The stabilization device as claimed in claim 37, wherein said second interconnection mechanism includes a tension link nut.

20 39. The stabilization device as claimed in claim 30, wherein said compression zone does not include a set screw.

40. The stabilization device as claimed in claim 30, wherein the first attachment device and the second attachment device are separated by a distance, said first rod member having a first length, said second rod member having a second length, and wherein said
25 distance is greater than either of said first length or said second length.

41. The stabilization device as claimed in claim 30, wherein said first rod member includes an external surface having a surficial feature selected from the group consisting of: roughening, texturing, ridges, valleys, indentations, projections, coatings, and embossing.

42. The stabilization device as claimed in claim 30, wherein said first rod member
30 is made of a material selected from the group consisting of stainless steel and titanium.

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43. The stabilization device as claimed in claim 32, wherein said half-cylinder sections have an inner surface, said inner surface includes a surficial feature selected from the group consisting of: roughening, texturing, ridges, valleys, indentations, projections, coatings, and embossing.

5 44. The stabilization device as claimed in claim 31, wherein said at least two portions are made of a material selected from the group consisting of stainless steel and titanium.

45. A spinal stabilization device for securing at least two vertebra, the at least two vertebra including a first vertebra having been fitted with a first attachment device and a
10 second vertebra having been fitted with a second attachment device, the stabilization device comprising:

a first rod member;

a first interconnection mechanism for attaching said first rod member to the first attachment device;

15 a clamp having a lower clamp portion and an upper clamp portion, said clamp portions including:

an interlocking zone that operatively engages at least a portion of said first rod member; and

a securing zone in spaced relation to said interlocking zone; and

20 a second interconnection mechanism for attaching said securing zone of said clamp to the second attachment device;

wherein said interlocking zone of said clamp is placed into compression against said at least a portion of said first rod member by tightening said securing zone of said clamp with said second interconnection mechanism.

25 46. The stabilization device as claimed in claim 45, wherein said lower clamp portion and said upper clamp portion are substantially half-cylinder sections.

47. The stabilization device as claimed in claim 45, wherein at least a portion of said lower clamp portion and said upper clamp portion at least partially surround a portion of said first rod member at said interlocking zone.

30 48. The stabilization device as claimed in claim 45, wherein said lower and upper clamp portions each include an opening for receiving said first rod member.

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49. The stabilization device as claimed in claim 45, wherein said first interconnection mechanism includes a tension link.

50. The stabilization device as claimed in claim 49, wherein said first interconnection mechanism includes a tension link nut.

5 51. The stabilization device as claimed in claim 45, wherein said second interconnection mechanism includes a tension link.

52. The stabilization device as claimed in claim 51, wherein said second interconnection mechanism includes a tension link nut.

10 53. The stabilization device as claimed in claim 45, wherein said first interconnection mechanism includes an extended tension link shaft.

54. The stabilization device as claimed in claim 45, wherein said second interconnection mechanism includes an extended tension link shaft.

55. The stabilization device as claimed in claim 45, wherein said interlocking zone does not include a set screw.

15 56. The stabilization device as claimed in claim 45, wherein said interlocking zone includes a set screw.

57. The stabilization device as claimed in claim 45, wherein said securing zone includes at least one receptacle.

20 58. A bone stabilization assembly for securing a first bone segment to a second bone segment, comprising:

first and second attachment devices each including a first end and a second end, said first end having threads for inserting into the bone segments, said second end having an enlarged area having a hollow core bordered by curved walls and an aperture therethrough;

25 first and second tension links each including a proximal end and a distal end, said proximal end having a tension link head and said distal end having a threaded shaft, said tension link head rotatably mounted within said hollow core and maintained therein by contact with said curved walls, said threaded shaft extending through said aperture of said attachment devices;

30 a first rod member having a socket for accepting said enlarged area of said first attachment device and a tension link cavity for passing said shaft of said first tension link

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therethrough, said socket securable against said first attachment device by a link nut threaded over said shaft of said first tension link;

a clamp having a lower clamp portion and an upper clamp portion, each clamp portion including:

5 an interlocking zone that operatively engages at least a portion of said first rod member; and

a securing zone in spaced relation to said interlocking zone, each securing zone including a tension link cavity for passing said shaft of said second tension link therethrough,

10 wherein at least one said securing zone includes a receptacle adapted to accept said enlarged area of said second attachment device;

wherein said interlocking zones of said clamp are placed into compression against said at least a portion of said first rod member by tightening a tension link nut over said shaft of said second tension link.

15 59. The assembly as claimed in claim 58, wherein said attachment devices are pedicle screws.

60. The assembly as claimed in claim 58, wherein said shafts are extended.

20 61. A spinal stabilization device for securing at least two vertebra, the at least two vertebra including a first vertebra having been fitted with a first attachment device and a second vertebra having been fitted with a second attachment device, the stabilization device comprising:

an interior rod member having a socket including a cavity therethrough, and a rod portion;

a first connector for attaching said socket to the first attachment device;

25 a second rod member including:

a compression zone that operatively engages at least a portion of said rod portion; and

a securing zone in spaced relation to said compression zone; and

30 a second connector for attaching said securing zone of second rod member to the second attachment device;

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wherein said compression zone of said second rod member is placed into compression against said at least a portion of said rod portion by tightening said securing zone of said second rod member with said second connector.

5 62. The device as claimed in claim 61, wherein said second rod member includes a lower clamp portion and an upper clamp portion.

 63. The device as claimed in claim 61, wherein said first connector comprises a tension link and tension link nut.

 64. The device as claimed in claim 63, wherein a portion of said tension link passes through said cavity.

10 65. The device as claimed in claim 63, further comprising an extended tension link shaft.

 66. The device as claimed in claim 61, wherein said second connector comprises a tension link and tension link nut.

15 67. The device as claimed in claim 66, further comprising an extended tension link shaft.

 68. In subcombination, a bone stabilization device for connecting a first area of bone to a second area of bone, the device used in combination with a first attachment device having a first interconnection mechanism, and a second attachment device having a second interconnection mechanism, said stabilization device comprising:

20 a first rod member;

 a second rod member including:

 an interlocking zone that operatively engages at least a portion of said first rod member; and

 a securing zone in spaced relation to said interlocking zone; and

25 wherein said interlocking zone of said second rod member is operatively interlocked with said at least a portion of said first rod member by tightening said securing zone of said second rod member with either of the first or second interconnection mechanisms.

 69. The device as claimed in claim 68, wherein said second rod member includes a lower clamp portion and an upper clamp portion.

30 70. The device as claimed in claim 68, wherein said securing zone includes a receptacle.

71. The device as claimed in claim 68, wherein said second rod member includes ridges.

72. The device as claimed in claim 68, wherein said first rod member includes a socket adapted to receive the first attachment device.

5 73. A surgically implanted bone stabilization apparatus for securing a first bone segment to a second bone segment, the apparatus comprising:

a first attachment device attached to the first bone segment;

a second attachment device attached to the second bone segment;

a first rod member;

10 a first interconnection means for attaching said first rod member to said first attachment device;

a second rod member including an interlocking zone for operatively engaging at least a portion of said first rod member; and

15 a second interconnection means for attaching said second rod member to said second attachment device;

wherein said interlocking zone of said second rod member is interlocked with said at least a portion of said first rod member by tightening said second interconnection means.

74. The apparatus as claimed in claim 73, wherein said first interconnection means comprises a tension link and a tension link nut.

20 75. The apparatus as claimed in claim 73, wherein said second interconnection means comprises a tension link and a tension link nut.

76. The apparatus as claimed in claim 73, wherein said second rod member includes a lower clamp portion and an upper clamp portion.

25 77. The apparatus as claimed in claim 73, wherein said first attachment device is a pedicle screw.

78. The apparatus as claimed in claim 73, wherein said second attachment device is a pedicle screw.

30 79. A method of stabilizing a first vertebra to a second vertebra, the method comprising the steps of:

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(a) attaching a first attachment device to the first vertebra and a second attachment device to the second vertebra, at least the second attachment device having a hollow core and a central aperture;

5 (b) connecting a first rod member to the first attachment device using a first interconnecting mechanism;

(c) inserting a tension link having a shaft and a tension link head into the hollow core of the second attachment device such that the shaft of the tension link extends through the central aperture of the second attachment device;

10 (d) installing a second rod member having:
an interlocking zone for clamping at least a portion of the first rod member; and

a securing zone in spaced relation to the interlocking zone,
said installing step further comprising passing the shaft of the tension link through a tension link cavity in the second rod member; and

15 (e) securing the second rod member to said second attachment device and the at least a portion of the first rod member by threading and tightening a tension link nut onto the shaft of the tension link.

80. The method as claimed in claim 79, wherein the first interconnecting mechanism comprises a tension link and link nut.

20 81. The method as claimed in claim 79, wherein the first interconnecting mechanism comprises receptacle formed in the end of the first rod member.

82. The method as claimed in claim 79, wherein the second rod member comprises a lower clamp portion and an upper clamp portion.

25 83. The method as claimed in claim 82, wherein the securing zone of the second rod member includes a receptacle at one end of the lower and upper clamp portions.

84. The method as claimed in claim 79, wherein the shaft of the tension link is an extended shaft.

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